K011444

AUG - 8 2001

510K Summary

Description of the Device:

The Anspach eMax drill system is an electrically powered drill motor with a series of attachments designed for use on the bones of the cranium and spine. The system components include a control console, the motor hand piece and attachments, and a foot control switch. The control console supplies power to the motor through a detachable cable. The control console has an integrated air pump that supplies a continuous flow of air to the hand piece through tubing in the power cable to cool the motor while in use. In addition, there is an optional peristaltic irrigation pump integrated into the control console that can supply irrigation fluid to the surgical site through external sterile tubing. The motor speed is displayed by a tachometer on the console. A touch pad on the console allows an assistant to vary the maximum speed and direction of rotation of the motor and control the function of the irrigation pump. The surgeon controls the motor and irrigation pump by use of a foot control switch attached to the control console by a cable. Pedals on the foot control allow the surgeon to vary the speed and direction of rotation of the drill. There is also an optional, detachable hand control that can be attached directly to the hand piece. Selection for use of the hand control or foot control is done on the touch pad on the control console. Motor attachments include a series of straight and angled nosepieces and burrs as well as sagittal, reciprocating and oscillating saw attachments. The system components are detailed in Appendix 2.

Comparison of New Device to Predicate Device

The device is substantially equivalent to the Anspach MicroMax pneumatic drill system (K965080). The performance characteristics are nearly identical to those of the MicroMax. The means of securing the attachments to the motor hand piece is the same as the MicroMax. The attachments are the same with the addition of sagittal, reciprocating and oscillating saw attachments for the eMax.

	eMax	Micromax
Intended Use	Cutting and shaping bone	Cutting and shaping bone
Power Source	Electric	Pneumatic
Speed	up to 80,000 RPM	up to 75,000 RPM
Stall Torque	3.9 inch-ounces	5.0 inch-ounces
Motor Weight	3.68 ounces	2.0 ounces
Motor Length	4.9 inches	3.5 inches
Materials	same	same
Method of use	same	same
Attachments	multiple burrs and nosepieces	multiple burrs and nosepieces
Means of securing attachments	same	same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2001

William E. Anspach, III, M.D.
Vice President, Research and
Development Regulatory
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K011444
Trade/Device Name: Anspach eMax Drill System
Regulation Number: 882.4360, 874.4250
Regulatory Class: II
Product Code: HBC, ERL
Dated: May 7, 2001
Received: May 11, 2001

Dear Dr. Anspach:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011444

Device Name: Anspach eMax Drill System

Indications For Use: Cutting and shaping bone including spine and cranium.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDEI

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011444

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_

(Optional Forma